

## HL7 SPL Working Group Process Communication Forum Telecon

Wednesday, June 17, 2009

Check out the SPL Working Group WIKI @:  
<http://spl-work-group.wikispaces.com>

### Questions on SPL:

ER/DL regulatory questions? Send to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)  
SPL technical questions? Send to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)

### Meeting Minutes:

#### Training sessions

- The FDA Data Standards Council's website was updated Tuesday, June 16, 2009, to include a new SPL Release Four Training session – Session 16 - Accelerated Course.

This one-hour course is offered for companies who need to learn how to electronically submit or request an NDC Labeler Code, register their drug establishments and list their drug products for **immediate** submission of SPL Release Four documents.

The information about this course is available on the web page accessible via this hyperlink:  
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>.

DIA - August 11 - 12 check at [www.diahome.org](http://www.diahome.org) for more information.  
GphA - tbd, October

Update from 10Jun09 Face to face

Slides at: <http://spl-work-group.wikispaces.com/Training>

### **DUNS Number:**

*Can anyone request a number for their suppliers, contractors, etc? Yes.*

*FDA will obtain DUNS numbers for a sponsor that 'refuses' to provide one from D&B.*

- Some companies of Europe have to register in-country with local government offices before a DUNS number can be assigned.

### **Establishment Registration**

- FDA will (in future) validate against the operators listed in the ER and DL  
FDA will (in future) validate against telephone numbers, Tel #s must have hyphens according to country style of presentation.  
FDA requires post codes for all countries not on the exception list.

- *Importer info is not needed if the facility doesn't ship directly to the US  
US Agent should be the company name, and have a DUNS number.  
Correspondence will be sent to the e-mail address of the contact name.*
- *What's the difference between the Importer of Record vs the definition of Importer on the SPL (Ship to: address)  
Importer of record = the entity responsible for paying tariffs OR the mailing address.  
Name, DUNS number, telephone number, e-mail address.*
- *Have to have a mechanism for verifying DUNS information – one way is to request info from D&B*

Some type of Guidance / document coming from Import staff for further information about Importer questions. No time frame on when this guidance will be released.

- FEI numbers will still be used for inspections. Companies will still be assigned an FEI number upon request. DUNS number will be used as the registration number for the eDRLS system.
- If there are issues about supply of a no-longer-available paper form, contact your local District Director as part of your conflict resolution process.
- Business Operations list will be expanded. For instance, API Manufacturer is expected to be added.
- *Why was ANALYSIS separated as a Business Operation? Manufacturing used to encompass a variety of functions (including ANALYSIS)*
- *Use three letter ISO-3166 code for Country. Exception: for Puerto Rico, do not use country code PRI. Use country = USA and state code = PR.*

Duplicative labeling submissions – future guidance to be issued. This references the current practice of submitting an SPL via the Application Review path and a duplicate of the SPL via the eList pathway.

#### Link to Data Standards Manual Monographs:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/default.htm>

#### Link specifically to Packaging terms:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071748.htm>

#### Update from Weekly FDA SPLr4 Q&A sessions

A weekly SPL R4 Q&A/Training session to respond to technical questions related to SPL is being offered to individuals responsible for the preparation and submission of drug establishment registration and drug listing information to the FDA.

June 8, 2009 – December 28, 2009

Mondays (except June 22, 2009, & Federal holidays)

11:30 a.m. – 12:00 p.m., EST

Audio conference details:  
Telephone number: 1-866-775-9435  
Participant pass code: 2219058

## Questions & Answers from June 15, 2009 Q&A Session

Question	Answer
How do I represent dose range?	Include only the upper value of the dose range for Biologics
How do I include a complex of active ingredients? Can I get a UNII for the complex?	Use a UNII for each active ingredient
How do I include a strength for each element of a complex?	Try to include the most clinical relevant strengths. You should submit the file officially. It will fail, and the FDA can provide immediate feedback. Also send an e-mail to the SPL mailbox to alert staff of the file.
What if I have the same product code at the part level and the kit level?	The marketing start date is the date that the FDA is permitted to post the file on DailyMed. If you have a product that needs to be imported, but won't be marketed for some time, put a date far in the future. The Import staff will have access to the file, but the file will not be publicly available on DailyMed.
Please clarify the marketing date?	Revised date in R3 was the date that FDA received the file in the ELIPS system. In R4, the revision date is set by the sponsor.
Can the revised date be the same as effective date?	FDA doesn't accept any special characters. Replace the decimal point with a semi-colon (2.5 would be 2;5)
Imprint codes - can you include a decimal point?	Suggest that you include all the previous metadata. Leave out the manufacturer in the Listing file. If the marketing end dates are included, but there isn't an Establishment, the file will still pass validation (on this criterion)
Content of labeling - discontinued manufacturing. What do we include?	
Change in packaging information - seems to be failing validation?	If the product has already been transmitted at least once to DailyMed. All of the R3 files were reloaded into the new system. Any changes that affect trade name, generic name, and packaging. Depending on the specific packaging change, and if the FDA agrees, request that the R3 file be removed, or that there is a disagreement on the packaging information. Attach the xml file to the letter to SPL, and also a link to the DailyMed records.
Drug Listing requirement for products without much activity - might not have a change every year - what should we do?	FDA considering the use of a No Change notification for a Drug Listing with no activity in a certain year. Not yet implemented.
Is a third-party warehouse considered an importer? And, if so, how would it be listed?	Where it's coming from, where it's going to - captured in the Establishment Registration form.
When you include the importer information, is it ok to include a representative from your company?	You can include the importer (company) name, the telephone and e-mail of the contact person.
Representative sample of labeling for a new listing - as long as the only difference is the strength?	
Still have to submit PDF of the package label with the Annual Report	The Review Division might want to see the PDFs.

## Sub team updates

### **Medical Devices**

on hold – June 4 ... quick review of the comments received, comments sent to Terrie Reed. No timeline or indication of how SPL would be used – for ER? For DL?

### **Biologics**

Seeing differences in timing of documents – Final DRAFT SPL being asked for before an approval letter with CBER; CBER is asking for Final SPL with first use

### **ER/DL update**

Did the approval letter include a timing of 14 days? No. Process is evolving w/in CBER?

### **OTC update -**

discussions about where to post files (should OTC Monograph products be posted to DailyMed?), Project PILLBOX; next meeting 29<sup>th</sup> June

### **Generics**

June 2 – Lonnie joined for Q&A. Next session on June 30.

Veterinary medicine

No additional updates from Veterinary Medicine Subteam

**Next meeting scheduled for Wednesday, July 1, 2009 from 1 – 2:30.**

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